K083462

FEB 27 2009

510 (k) Summary for the Dimension Vista® System Enzyme 5 Calibrator (KC350)

510 (k) Number:

Analyte: Lactate dehydrogenase

Type of Test: Calibrator Material

Applicant:

Siemens Healthcare Diagnostics Inc
P.O. Box 6101
Newark, DE 19714-6101
Helen M. Lee
Regulatory Affairs and Compliance Manager
Office Phone: 302.631.8706
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Proprietary and Established Name:

Dimension Vista® System Enzyme 5 Calibrator

Regulatory Information:

Regulation Section: 21 CFR § 862.1150 - Calibrator
Classification: Class II
Product Code: JIT – Calibrator, Secondary

Panel: Clinical Chemistry

Intended Use:

The Enzyme 5 Calibrator (ENZ 5 CAL) is an *in vitro* diagnostic product for the calibration of the lactate dehydrogenase (LDI) method on the Dimension Vista® System.

Device Description:

ENZ 5 CAL is a liquid, bovine serum albumin based product containing lactate dehydrogenase (chicken heart). The calibrator, one level (Calibrator A), comes packaged with three vials at 1.5 mL per vial. System water, the zero level calibrator does not come packaged with the calibrator.

510 (k) Summary for the
Dimension Vista® System Enzyme 5 Calibrator (KC350)

Substantial Equivalence Information:

Comparison of the Dimension Vista® System Enzyme 5 Calibrator (proposed device) to the predicate Dimension® clinical chemistry system Enzyme I Calibrator.

Similarities

Item	New Device	Predicate Device
Analyte	Lactate dehydrogenase.	Lactate dehydrogenase.
Intended Use	For the calibration of the lactate dehydrogenase (LDI) method on the Dimension Vista® System. For *in vitro* diagnostic use.	For the calibration of the lactate dehydrogenase (LDI) method on the. Dimension® clinical chemistry system. For *in vitro* diagnostic use.
Matrix	Liquid bovine serum albumin base with lactate dehydrogenase of chicken liver origin.	Liquid bovine serum albumin base with lactate dehydrogenase of chicken liver origin.
Form	Liquid	Liquid
Traceability	IFCC *LD* at *37* ° C primary reference method.	IFCC *LD* at *37* ° C primary reference method

Differences

Item	New Device	Predicate Device
Calibrator Packaging	One Level – Calibrator A	Two Levels – Level 2 and Level 3
Calibration Levels	Two Levels: · System water is Level 1 · Calibrator A is Level 2	Three Levels: ·Purified Water Diluent or reagent grade water is Level 1 · Level 2 Calibrator · Level 3 Calibrator

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Standard/Guidance Documents Referenced:

1. Guidance: Guidance for Industry – Abbreviated 510 (k) Submissions for In Vitro Diagnostic Calibrators; February 22, 1999

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices – Application of risk management to medical devices

Performance Characteristics:

1. Stability:

Shelf-life

Target shelf life for the Dimension Vista® ENZ 5 CAL is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 2-8°C with control stored at -20°C and -70°C. The method is calibrated each month with the -70°C control material. The 2-8°C and -20°C materials are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Shelf life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Siemens Healthcare Diagnostics Inc.

Open Vial

Vials are opened on day zero. A quantity sufficient for multiple calibrations is removed; the vials are recapped and stored at 2-8°C. Opened vials are tested on days 0, 15 and 32; freshly opened vials are also tested on days 15 and 32.
An open vial, not on board the instrument, but recapped and stored at 2-8°C is stable for 30 days.

Punctured Vial

Vials are punctured on day zero with the appropriate quantity removed, leaving sufficient volume for one calibration and dead volume. Punctured vials are recapped and stored at 2-8°. Four recapped vials are tested on day zero. Two recapped vials and eight punctured vials are tested on approximately days 3, 8 and 15. Two freshly opened vials are tested at each test point.
A vial punctured by the instrument and stored on board is stable for seven days.

2. Traceability: The assigned values for the Dimension Vista® ENZ 5 CAL are assigned from Master pools that are traceable to the IFCC Reference Measurement Procedure.

510 (k) Summary for the
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Value Assignment:

Anchor Pool

Two levels of LD Anchor pools (Levels 2 and 3) are prepared using pooled human serum samples with normal and elevated LD values; the final target concentrations of Level 2=625 U/L and Level 3=1250 U/L. Values are assigned to the Anchor Pools by the IFCC LD Reference Measurement Procedure by a Reference Laboratory approved by the Joint Committee for Traceability in Laboratory Medicine (JCTLM). Level 1(system water) is assigned a value of zero U/L.

The reference laboratory uses the IFCC LD Reference Measurement Procedure to assign values to the Anchor Pools against calibrators with Reference Measurement Procedure values. The calibrators are prepared by the Reference Laboratory using pooled human sera with Reference Measurement Procedure values for the catalytic concentration of the LD enzyme. They are used for calibration of the Reference Laboratory measurements. The performance and the long term stability of the calibrators have been confirmed by the Reference Laboratory.

The Control used during the assignment of Anchor Pools at the Reference Laboratory is also produced and certified by the Reference Laboratory and is used to ascertain the accuracy of the test runs performed to assign values to the Siemens Anchor Pools.

Masterpool

Two levels of LD Masterpools (Levels 2 and 3) are produced by adding the appropriate volume of LD stock with a known concentration into an aqueous Bovine Serum Albumin matrix. Level 1 of the LD Masterpool, system water, is assigned zero U/L. Levels 2 and 3 of the LD Masterpool are assigned from Anchor Pool calibration curves, using three instruments and three lactate dehydrogenase (LDI) reagent lots. Each instrument is calibrated three times with Anchor Pools for a total of 9 curves. Values for five replicates each of Level 2 and Level 3 of the Masterpool are determined from each Anchor Pool curve, resulting in 45 replicates each for LD Masterpool Level 2 and Level 3. A commercial quality control material, Bio-rad Multiqual QC, assayed for the IFCC LD method, is used as a control in the assignment of the Masterpools. The LD Anchorpools and Masterpools are stored at -70°C.

510 (k) Summary for the
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3. Value Assignment (cont):

Commercial Calibrator

For commercial calibrators, a stock solution is made by adding LD powder gravimetrically to the stock solution at the target concentration. The commercial calibrator is made by adding calculated quantities of stock solution to the calibrator base at the appropriate concentration for Calibrator A. Before vial filling, the concentration of the calibrator is verified by measuring LD recovery on an instrument calibrated with LD Masterpools.

For value assignment of the commercial calibrators Siemens uses a three point LD Masterpool Linear curve. After filling, the final bottle values are assigned to Calibrator A, using LD Masterpools. The final bottle values of the commercial lots are assigned against the LD Masterpools using three instruments and three LDI reagent lots. Each instrument is calibrated three times with LD Masterpools for a total of 9 standard curves. Five replicates of the commercial lot Calibrator A are tested with each Masterpool curve yielding 45 replicates. The assigned Calibrator A value is the mean of the 45 replicates. A previously assigned commercial lot is used as the control for the assignment of new commercial lots.

Comments on Substantial Equivalence:

Both the proposed Dimension Vista® Enzyme 5 Calibrator and the predicate Dimension® Enzyme I Calibrator are traceable to IFCC reference method and are used to calibrate IFCC traceable lactate dehydrogenase methods.

Conclusion:

The Dimension Vista® Enzyme 5 Calibrator is substantially equivalent to Dimension® Enzyme I Calibrator based upon the information above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Siemens Healthcare Diagnostics
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M/S 514
Newark, DE 19714-6101

FEB 27 2009

Re: k083462
Trade/Device Name: Dimension Vista® System Enzyme 5 Calibrator (ENZ 5 CAL)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 21, 2008
Received: December 15, 2008

Dear Helen M. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k083462

Device Name: Dimension Vista® System Enzyme 5 Calibrator (ENZ 5 CAL)

Indication For Use: The ENZ 5 CAL is an *in vitro* diagnostic product for the calibration of the lactate dehydrogenase (LDI) method on the Dimension Vista® System.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083462